

## SUBCHAPTER 25K – DRUGS/PHARMACY

### SECTION .0100 – RESERVED FOR FUTURE CODIFICATION

#### 10A NCAC 25K .0100 RESERVED FOR FUTURE CODIFICATION

### SECTION .0200 – PHARMACY SERVICES

#### 10A NCAC 25K .0201 PHARMACY SERVICES

*History Note:* Authority G.S. 90-85.26; 108A-25(b); 108A-54; 42 C.F.R. 440.90; 42 CFR 447.331; S.L. 1985, c. 479, s. 86; 42 U.S.C. 1396r-8(d)(1)(A); S.L. 2009-451; Eff. September 30, 1977; Readopted Eff. October 31, 1977; Amended Eff. January 1, 1984; Recodified from 10 NCAC 26B .0116 Eff. October 1, 1993; Recodified from 10 NCAC 26B .0117 Eff. January 1, 1998; Amended Eff. May 1, 2010; Transferred from 10A NCAC 22O .0118 Eff. May 1, 2012; Repealed Eff. June 1, 2019.

### SECTION .0300 - DRUG USE REVIEW BOARD

#### 10A NCAC 25K .0301 ESTABLISHMENT

The Division of Health Benefits will establish a Drug Use Review Board. The Drug Use Review Board shall not have rule making authority. The Division of Health Benefits shall have the authority to reject recommendations of the Drug Use Review Board. In the event of such rejections, Division of Health Benefits shall notify the Drug Use Review Board, in writing, of the reasons for its action and allow the DUR Board an opportunity to reconsider its recommendation or decision.

*History Note:* Authority G.S. 108A-68; Social Security Act Section 1927(g); Eff. January 4, 1993; Transferred from 10A NCAC 22M .0101 Eff. May 1, 2012; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 23, 2016; Amended Eff. March 1, 2020.

#### 10A NCAC 25K .0302 MEMBERSHIPS

(a) The DUR Board shall consist of the Division of Health Benefits Drug Use Review Coordinator and the following appointed positions:

- (1) five licensed and practicing physicians;
- (2) five licensed and practicing pharmacists; and
- (3) at least two additional individuals with knowledge and expertise in one or more of the following:
  - (A) prescribing of Medicaid covered outpatient drug;
  - (B) dispensing and monitoring of Medicaid covered outpatient drugs;
  - (C) drug use review, evaluation, and intervention; or
  - (D) medical quality assurance.

(b) The Division shall appoint members of the DUR Board for up to three one-year terms. Either party shall have the right to terminate the membership upon five days notice in writing to the other party. The DUR Coordinator is not an appointed member, is not subject to the term requirement and only serves on the Board while actively employed with DHB as the DUR Coordinator.

(c) The North Carolina Association of Pharmacists, the North Carolina Medical Society, and the Old North State Medical Society shall be asked by DHB's DUR Coordinator to make nominations for some of the positions on the Board. The Director may accept or reject nominations received.

*History Note:* Authority G.S. 108A-68; 42 U.S.C. 1396r-8(g)(3)(B); Eff. January 4, 1993;

*Amended Eff. April 1, 2010;*  
*Transferred from 10A NCAC 22M .0102 Eff. May 1, 2012;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 23, 2016;*  
*Amended Eff. March 1, 2020.*

#### **10A NCAC 25K .0303 CHAIRMEN**

One pharmacist and one physician shall serve as co-chairmen of the Board. Beginning in calendar year 1996, each co-chairman shall be elected by his peers, the term of the chairmen shall be one year, and membership on the Board of at least one previous year shall be required to establish eligibility for serving as the chairman.

*History Note: Authority G.S. 108A-68; Social Security Act Section 1927(g);*  
*Eff. January 4, 1993;*  
*Transferred from 10A NCAC 22M .0103 Eff. May 1, 2012;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 23, 2016.*

#### **10A NCAC 25K .0304 ACTIVITIES**

(a) The activities of the Drug Use Review Board shall include but are not limited to making recommendations for rules to the Division Directors for Medicaid recipients for the following:

- (1) retrospective review of Medicaid claims information for drug therapy problems;
- (2) application of standards for prospective and retrospective Drug Use Review;
- (3) ongoing interventions for prescribers, pharmacists, and recipients targeted toward therapy problems identified in the course of Medicaid retrospective drug use reviews;
- (4) preparation of an annual report to the Division of Health Benefits on the Drug Use Review process;
- (5) programs to educate pharmacists and prescribers on common drug therapy problems identified in the Medicaid drug use reviews with the aim of improving prescribing or dispensing practices.

(b) The criteria and standards for the drug therapy review adopted by the Division upon recommendation by the Drug Use Review Board shall be available to pharmacists, prescribers, and the general public.

*History Note: Authority G.S. 108A-68; Social Security Act Section 1927(g);*  
*Eff. January 4, 1993;*  
*Transferred from 10A NCAC 22M .0104 Eff. May 1, 2012;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 23, 2016;*  
*Amended Eff. March 1, 2020.*

### **SECTION .0400 - PROSPECTIVE DRUG REVIEW**

#### **10A NCAC 25K .0401 PATIENT COUNSELING**

(a) Rule 21 NCAC 46 .2504, as adopted by the North Carolina Board of Pharmacy, shall apply to Medicaid, and is hereby incorporated by reference including subsequent amendments and editions.

(b) If a pharmacy fails to comply with the requirements of 21 NCAC 46 .2504, any claim for reimbursement associated with the pharmacy's non-compliance shall be denied, or if already paid, shall be recouped.

*History Note: Authority G.S. 108A-54; 108A-54.1B; 108A-68; 42 U.S.C. 1396r-8(g)(2)(A)(ii);*  
*Eff. June 1, 1993;*  
*Amended Eff. March 1, 2010;*  
*Transferred from 10A NCAC 22M .0201 Eff. May 1, 2012;*  
*Readopted Eff. June 1, 2019.*

### **SECTION .0500 - RETROSPECTIVE DRUG USE REVIEW (DUR)**

#### **10A NCAC 25K .0501 RETROSPECTIVE DRUG USE REVIEW (DUR)**

*History Note: Authority G.S. 108A-68; 42 U.S.C. 1396R-8(2)(b)-(C);*  
*Eff. January 4, 1993;*  
*Amended March 1, 2010;*

*Transferred from 10A NCAC 22M .0301 Eff. May 1, 2012;  
Expired Eff. August 1, 2016 pursuant to G.S. 150B-21.3A.*

#### **10A NCAC 25K .0502 SCREENING AND PATTERN ANALYSIS**

At least quarterly, the Medicaid drug claims, in conjunction with other Medicaid claims as needed for clinical purposes, shall be subjected to screening against standards approved by the Drug Use Review Board. The objective of the screening is to identify patterns of behavior involving prescribers and pharmacists, or patterns associated with specific drugs or groups of drugs. Health care patterns of individual Medicaid recipients shall be screened. In addition, individual incidences of screen failure associated with a specific recipient shall be identified for intervention alerts.

*History Note: Authority G.S. 108A-68; Social Security Act Section 1927(g);  
Eff. January 4, 1993;  
Transferred from 10A NCAC 22M .0302 Eff. May 1, 2012;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 23, 2016.*

#### **10A NCAC 25K .0503 INTERVENTIONS**

The primary objective of the retrospective Drug Use Review is to provide education to pharmacists and prescribers, both individually and collectively, in order to improve prescribing and dispensing practices. The intervention and educational programs shall be developed by the Drug Use Review Board and shall be updated as more information is available from the retrospective review process.

The Drug Use Review Board may establish referral processes to the Board of Pharmacy, the Board of Medical Examiners, the Board of Dental Examiners, other health care licensing agencies, or the Division of Health Benefits Program Integrity Section for individual pharmacists or prescriber who continue to demonstrate patterns of prescribing or dispensing which put the Medicaid recipient at risk from drug therapy problems even after repeated warnings through Drug Use Review interventions.

*History Note: Authority G.S. 108A-68; Social Security Act Section 1927(g);  
Eff. January 4, 1993;  
Transferred from 10A NCAC 22M .0303 Eff. May 1, 2012;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 23, 2016;  
Amended Eff. March 1, 2020.*

#### **10A NCAC 25K .0504 COMPLIANCE MONITORING**

The prescriber's and pharmacist's responses to the interventions undertaken as a result of the retrospective Drug Use Review shall be tracked. The Drug Use Review Board may establish selection criteria for intensified review and monitoring of individual pharmacists and prescribers.

*History Note: Authority G.S. 108A-68; Social Security Act Section 1927(g);  
Eff. January 4, 1993;  
Transferred from 10A NCAC 22M .0304 Eff. May 1, 2012;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 23, 2016.*